DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1583d

CERTIFIED MAIL
RETURN RECEIPT REQUEST

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

July 30, 2001

Claude Vidal
President
VIR Engineering, Inc.
5580 Calle Real
Santa Barbara, CA 93111

WL-69-01

Dear Mr. Vidal:

During an inspection of your firm located in Santa Barbara, California, on July 2 to 5, 2001, our investigator determined that your firm manufactures disposable scalpel blade removers and containers, commonly known as sharp containers. Disposable scalpel blade removers are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of management with executive responsibility to appoint and document a member of management as management representative with the authority over and responsibility for ensuring that quality system requirements are effectively established and maintained [21 CFR 820.20(b)(3)]. Specifically, our investigation determined that one individual has responsibility for all manufacturing and quality assurance activities and these duties have not been formally defined.

2. Failure to control quality audit procedures and to conduct quality audits to assure that the quality system is in compliance with established quality system requirements [21 CFR 820.22]. Specifically, no internal quality audits have been conducted since 12/2/1996.

3. Failure to implement and control procedures for management reviews to ensure that the quality system satisfies the requirements of the Quality System Regulation and the quality policy and objectives of the firm [21 CFR 820.20(c)]. Specifically, no management reviews have been conducted.

4. Failure to establish procedure for complaint handling activities to ensure that all complaints are processed in a uniform and timely manner and are evaluated to determine whether the complaint should be filed as a Medical Device Report [21 CFR 820.198(a)]. Specificially, no procedures have been established for receiving, reviewing or evaluating complaints to determine if an investigation is warranted and the results of the investigation or explanation not to conduct an investigation is documented. Additionally, there is no procedure to evaluate complaints to determine if a Medical Device Report should be filed.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320